**ISO/IEC 17025:2017 Management Overview Executive Summary**

**General requirements for the competence of testing and calibration laboratories**

# Introduction

## General Overview

ISO/IEC 17025:2017 has been developed to promote confidence in laboratory operations by specifying requirements that enable laboratories to demonstrate competent operation and ability to generate valid results. This standard represents the global benchmark for testing and calibration laboratory competence, incorporating risk-based thinking and providing greater flexibility in requirements for processes, procedures, and organizational responsibilities. The standard requires laboratories to plan and implement actions to address risks and opportunities, establishing a basis for management system effectiveness and improved results.

## Risk-Based Approach

The standard emphasizes risk-based thinking throughout laboratory operations, enabling reduction in prescriptive requirements while maintaining performance-based standards. Laboratories are responsible for deciding which risks and opportunities need to be addressed, with actions proportional to potential impact on result validity. This approach provides operational flexibility while ensuring result reliability and stakeholder confidence.

## International Recognition

The standard facilitates cooperation between laboratories and other bodies, assists in information and experience exchange, and supports harmonization of standards and procedures. International acceptance of results is facilitated when laboratories conform to this standard, providing global recognition of laboratory competence and technical capability.

# Section 1: Scope

ISO/IEC 17025:2017 specifies general requirements for competence, impartiality, and consistent operation of laboratories performing testing, calibration, and sampling activities. The standard applies to all organizations performing laboratory activities regardless of personnel number, encompassing various laboratory types and operational configurations. Laboratory customers, regulatory authorities, peer-assessment organizations, accreditation bodies, and other stakeholders use this standard to confirm or recognize laboratory competence.

# Section 2: Normative References

The standard references ISO/IEC Guide 99 (International vocabulary of metrology) and ISO/IEC 17000 (Conformity assessment — Vocabulary and general principles), providing essential terminology and concepts for understanding measurement science and conformity assessment principles applicable to laboratory operations.

# Section 3: Terms and Definitions

Key definitions include impartiality (presence of objectivity), complaint (expression of dissatisfaction), interlaboratory comparison, intralaboratory comparison, proficiency testing, laboratory (body performing testing, calibration, or sampling), decision rule, verification, and validation. These terms establish the foundation for understanding laboratory competence requirements and operational expectations.

# Section 4: General Requirements

## Impartiality

Laboratory activities must be undertaken impartially with structures and management safeguarding impartiality. Management must be committed to impartiality, and laboratories must not allow commercial, financial, or other pressures to compromise impartiality. Risks to impartiality must be identified on an ongoing basis, including those arising from activities, relationships, or personnel relationships, with demonstration of risk elimination or minimization.

## Confidentiality

Laboratories must be responsible for managing all information obtained or created during laboratory activities through legally enforceable commitments. Customer information must be protected as confidential unless made publicly available by the customer or agreed between laboratory and customer. Personnel must maintain confidentiality of all information obtained during laboratory activities except as required by law.

# Section 5: Structural Requirements

## Legal Entity and Responsibility

Laboratories must be legal entities or defined parts of legal entities legally responsible for laboratory activities. Management with overall laboratory responsibility must be identified, and the range of conforming laboratory activities must be defined and documented. Laboratory activities must meet standard requirements, customer requirements, regulatory authority requirements, and recognition organization requirements.

## Organizational Structure

Organizations must define organizational and management structure, specify personnel responsibilities and authorities, and document procedures ensuring consistent application and result validity. Personnel must have authority and resources for duties including management system implementation, deviation identification, corrective action initiation, performance reporting, and activity effectiveness assurance.

## Communication and Change Management

Management must ensure effective communication regarding management system effectiveness and requirement importance, with system integrity maintenance during planned changes. This ensures organizational alignment and system reliability during operational transitions.

# Section 6: Resource Requirements

## Personnel Competence

All personnel affecting laboratory activities must act impartially, be competent, and work according to the management system. Competence requirements must be documented for each function, with personnel having competence to perform assigned activities and evaluate deviation significance. Procedures must be established for competence determination, personnel selection, training, supervision, authorization, and competence monitoring.

## Facilities and Equipment

Facilities and environmental conditions must be suitable for laboratory activities without adversely affecting result validity. Environmental condition requirements must be documented, monitored, controlled, and recorded when influencing results. Equipment must be appropriate for correct performance with documented procedures for handling, transport, storage, use, and maintenance.

## Metrological Traceability

Measurement results must have established and maintained metrological traceability through documented unbroken calibration chains contributing to measurement uncertainty. Results must be traceable to the International System of Units through competent laboratory calibration, certified reference materials, or direct SI unit realization.

## External Providers

Externally provided products and services affecting laboratory activities must be suitable, with procedures for defining requirements, evaluation criteria, provider selection, performance monitoring, and conformity verification. External provider communication must include product and service specifications, acceptance criteria, competence requirements, and planned laboratory activities at provider premises.

# Section 7: Process Requirements

## Contract and Method Management

Procedures must ensure requests, tenders, and contracts are adequately defined with laboratory capability and resource verification. Appropriate methods must be selected and communicated to customers, with latest valid versions used unless inappropriate. Method verification must be performed before introduction, with development planned and assigned to competent personnel.

## Validation and Sampling

Non-standard methods, laboratory-developed methods, and modified standard methods must be validated as extensively as necessary for application needs. Sampling plans and methods must address factors controlling subsequent testing or calibration result validity, with comprehensive documentation and record retention.

## Technical Records and Uncertainty

Technical records must contain sufficient information to facilitate factor identification affecting results and measurement uncertainty, enabling activity repetition under similar conditions. Measurement uncertainty evaluation is required for calibrations and testing, with appropriate analysis methods and contribution identification including sampling effects.

## Result Validity and Reporting

Procedures must monitor result validity through reference materials, alternative instrumentation, functional checks, working standards, intermediate checks, replicate tests, retained item testing, characteristic correlation, result review, intralaboratory comparisons, and blind sample testing. Results must be reviewed and authorized before release with comprehensive reporting including all agreed and required information.

# Section 8: Management System Requirements

## Management System Options

Laboratories must establish, document, implement, and maintain management systems supporting consistent requirement achievement and result quality assurance. Two options are available: Option A (minimum management system requirements) or Option B (ISO 9001-based management system capable of supporting requirements fulfillment).

## Option A Requirements

Minimum management system requirements include documentation control, record control, risk and opportunity actions, improvement processes, corrective actions, internal audits, and management reviews. These elements ensure systematic approach to laboratory management and continual improvement.

## Documentation and Control

Management system documentation must include policies and objectives for standard fulfillment with implementation at all organizational levels. Document control must ensure approval adequacy, periodic review, change identification, distribution control, unique identification, and obsolete document prevention.

## Risk Management and Improvement

Actions must address risks and opportunities to achieve intended results, enhance opportunities, prevent undesired impacts, and achieve improvement. Improvement opportunities must be identified and selected with necessary action implementation, customer feedback analysis, and management system enhancement.

## Internal Audits and Management Review

Internal audits must be conducted at planned intervals to verify management system conformity and effective implementation. Management reviews must evaluate continuing suitability, adequacy, and effectiveness with comprehensive input consideration and output decisions for improvement and change needs.

# Annex A: Metrological Traceability

## Traceability Establishment

Metrological traceability requires measurand specification, documented unbroken calibration chains to appropriate references, measurement uncertainty evaluation for each chain step, appropriate method performance, and technical competence evidence for each chain step. Systematic measurement error consideration is essential for traceability dissemination.

## Traceability Demonstration

Various methods demonstrate conformity including national metrology institute capabilities under CIPM MRA, accredited capabilities under ILAC arrangements, and other internationally accepted paths. The Joint BIPM, OIML, ILAC, and ISO Declaration provides specific guidance for international acceptability demonstration.

# Annex B: Management System Options

## Option Comparison

Both options achieve the same management system performance and compliance results. Option A provides minimum requirements while Option B allows ISO 9001-based systems. The choice depends on organizational preferences and existing management system infrastructure, with both ensuring laboratory competence demonstration.

## Key Success Factors

1. **Technical Competence**: Comprehensive personnel competence development and maintenance ensuring reliable result generation
2. **Impartiality Management**: Systematic identification and management of impartiality risks maintaining objectivity and credibility
3. **Method Validation**: Thorough validation of methods ensuring result reliability and fitness for intended use
4. **Uncertainty Evaluation**: Comprehensive measurement uncertainty assessment providing confidence in result accuracy
5. **Continual Improvement**: Regular monitoring, evaluation, and improvement ensuring continued competence and effectiveness

## Implementation Benefits

* **Technical Credibility**: Enhanced recognition of laboratory technical competence and result reliability
* **Global Acceptance**: International recognition facilitating result acceptance across borders and markets
* **Risk Management**: Systematic approach to identifying and managing risks affecting result validity
* **Operational Excellence**: Improved operational efficiency through systematic process approach and continual improvement
* **Stakeholder Confidence**: Enhanced confidence from customers, regulators, and other stakeholders in laboratory capability
* **Competitive Advantage**: Accreditation providing market differentiation and customer assurance
* **Regulatory Compliance**: Framework supporting compliance with applicable regulatory and legal requirements